Commissioner, e.g., model State and local ordinances, or personnel practices for reducing radiation exposure, issued under 42 U.S.C. 243 and 21 U.S.C. 360ii. These recommendations may, in the discretion of the Commissioner, be handled under the procedures established in §10.115, except that the recommendations will be included in a separate public file of recommendations established by the Division of Dockets Management and will be separated from the guidance documents in the notice of availability published in the FEDERAL REGISTER, or be published in the FEDERAL REGISTER as regulations under paragraph (a) of this section.

(d) *Agreements.* Formal agreements, memoranda of understanding, or other similar written documents executed by FDA and another person will be included in the public file on agreements established by the Division of Freedom of Information (ELEM–1029) under §20.108. A document not included in the public file is deemed to be rescinded and has no force or effect whatever.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989; 65 FR 56477, Sept. 19, 2000; 75 FR 16346, Apr. 1, 2010]

§10.95 Participation in outside standard-setting activities.

(a) *General.* This section applies to participation by FDA employees in standard-setting activities outside the agency. Standard-setting activities include matters such as the development of performance characteristics, testing methodology, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. FDA encourages employee participation in outside standard-setting activities that are in the public interest.

(b) *Standard-setting activities by other Federal Government agencies.* (1) An FDA employee may participate in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide.

(2) Approval forms and all pertinent background information describing the activity will be included in the public file on standard-setting activities established by the Division of Freedom of Information (ELEM–1029).

(3) If a member of the public is invited by FDA to present views to, or to accompany, the FDA employee at a meeting, the invitations will be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.

(4) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to the group or organization responsible for the activity.

(c) *Standard-setting activities by State and local government agencies and by United Nations organizations and other international organizations and foreign governments pursuant to treaty.* (1) An FDA employee may participate in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide.

(2) Approval forms and all pertinent background information describing the activity will be included in the public file on standard-setting activities established by the Division of Freedom of Information (ELEM–1029).

(3) The availability for public disclosure of records relating to the activity will be governed by part 20.

(4) If a member of the public is invited by FDA to present views to, or to accompany, the FDA employee at a meeting, the invitation will be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.

(5) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to the group or organization responsible for the activity.

(d) *Standard-setting activities by private groups and organizations.* (1) An FDA employee may engage in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide. A request for official participation must be made by the group or organization in writing, must describe the scope of the activity, and must demonstrate that

the minimum standards set out in paragraph (d)(5) of this section are met. Except as provided in paragraph (d)(7) of this section, a request that is granted will be the subject of a letter from the Commissioner or the center director to the organization stating—

(i) Whether participation by the individual will be as a voting or nonvoting liaison representative;

(ii) That participation by the individual does not connote FDA agreement with, or endorsement of, any decisions reached; and

(iii) That participation by the individual precludes service as the deciding official on the standard involved if it should later come before FDA. The deciding official is the person who signs a document ruling upon the standard.

(2) The letter requesting official FDA participation, the approval form, and the Commissioner's or center director's letter, together with all pertinent background information describing the activities involved, will be included in the public file on standard-setting activities established by the Division of Freedom of Information (ELEM–1029).

(3) The availability for public disclosure of records relating to the activities will be governed by part 20.

(4) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to the group or organization responsible for the activity.

(5) The following minimum standards apply to an outside private standard-setting activity in which FDA employees participate:

(i) The activity will be based upon consideration of sound scientific and technological information, will permit revision on the basis of new information, and will be designed to protect the public against unsafe, ineffective, or deceptive products or practices.

(ii) The activity and resulting standards will not be designed for the economic benefit of any company, group, or organization, will not be used for such antitrust violations as fixing prices or hindering competition, and will not involve establishment of certification or specific approval of individual products or services.

(iii) The group or organization responsible for the standard-setting activity must have a procedure by which an interested person will have an opportunity to provide information and views on the activity and standards involved, without the payment of fees, and the information and views will be considered. How this is accomplished, including whether the presentation will be in person or in writing, will be decided by the group or organization responsible for the activity.

(6) Membership of an FDA employee in an organization that also conducts a standard-setting activity does not invoke the provisions of this section unless the employee participates in the standard-setting activity. Participation in a standard-setting activity is subject to this section.

(7) The Commissioner may determine in writing that, because direct involvement by FDA in a particular standard-setting activity is in the public interest and will promote the objectives of the act and the agency, the participation is exempt from the requirements of paragraph (d)(1) (ii) and/or (iii) of this section. This determination will be included in the public file on standard-setting activities established by the Division of Freedom of Information (ELEM–1029) and in any relevant administrative file. The activity may include the establishment and validation of analytical methods for regulatory use, drafting uniform laws and regulations, and the development of recommendations concerning public health and preventive medicine practices by national and international organizations.

(8) Because of the close daily cooperation between FDA and the associations of State and local government officials listed below in this paragraph, and the large number of agency employees who are members of or work with these associations, participation in the activities of these associations is exempt from paragraphs (d)(1) through (7) of this section, except that a list of the committees and other groups of these associations will be included in the public file on standard-setting activities established by the Division of Freedom of Information (ELEM–1029).

(i) American Association of Food Hygiene Veterinarians (AAFHV).
(ii) American Public Health Association (APHA).
(iii) Association of American Feed Control Officials, Inc. (AAFCO).
(iv) Association of Food and Drug Officials (AFDO).
(v) AOAC INTERNATIONAL (AOAC).
(vi) Association of State and Territorial Health Officials (ASTHO).
(vii) Conference for Food Protection (CFP).
(viii) Conference of State Health and Environmental Managers (COSHEM).
(ix) Conference of Radiation Control Program Directors (CRCPD).
(x) International Association of Milk, Food, and Environmental Sanitation, Inc. (IAMFES).
(xi) Interstate Shellfish Sanitation Conference (ISSC).
(xii) National Association of Boards of Pharmacy (NABP).
(xiii) National Association of Departments of Agriculture (NADA).
(xiv) National Conference on Interstate Milk Shipments (NCIMS).
(xv) National Conference of Local Environmental Health Administrators (NCLEHA).
(xvi) National Conference on Weights and Measures (NCWW).
(xvii) National Environmental Health Association (NEHA).
(xviii) National Society of Professional Sanitarians (NSPS).

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 52 FR 35064, Sept. 17, 1987; 54 FR 9035, Mar. 3, 1989; 70 FR 40880, July 15, 2005; 70 FR 67651, Nov. 8, 2005; 76 FR 31469, June 1, 2011]

§ 10.100 Public calendar.

(a) *Public calendar*. A public calendar will be prepared and made publicly available by FDA each week showing, to the extent feasible, significant events of the previous week, including significant meetings with persons outside the executive branch, that involve the representatives of FDA designated under paragraph (c) of this section.

(1) Public calendar entries will include:

(i) Significant meetings with members of the judiciary, representatives of Congress, or staffs of congressional committees when the meeting relates to a pending court case, administrative hearing, or other regulatory action or decision;

(ii) Significant meetings, conferences, seminars, and speeches; and

(iii) Social events sponsored by the regulated industry.

(2) The public calendar will not include reports of meetings that would prejudice law enforcement activities (e.g., a meeting with an informant) or invade privacy (e.g., a meeting with a candidate for possible employment at FDA), meetings with members of the press, or meetings with onsite contractors.

(b) *Calendar entries*. The calendar will specify for each entry the date, person(s), and subject matter involved. If a large number of persons are in attendance, the name of each individual need not be specified. When more than one FDA representative is in attendance, the most senior agency official will report the meeting on the public calendar.

(c) *Affected persons*. The following FDA representatives are subject to the requirements of this section:

(1) Commissioner of Food and Drugs.
(2) Senior Associate Commissioners.
(3) Deputy Commissioners.
(4) Associate Commissioner for Regulatory Affairs.
(5) Center Directors.
(6) Chief Counsel for the Food and Drug Administration.

(d) *Public display*. The public calendar will be placed on public display at the following locations:

(1) Division of Dockets Management.
(2) Office of the Associate Commissioner for Public Affairs.
(3) The FDA home page, to the extent feasible.

[66 FR 6468, Jan. 22, 2001]

§ 10.105 Representation by an organization.

(a) An organization may represent its members by filing petitions, comments, and objections, and otherwise participating in an administrative proceeding subject to this part.

(b) A petition, comment, objection, or other representation by an organization will not abridge the right of a member to take individual action of a